PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	**Mehran Bashiri, Michael Davis**
Application No.:	**09/944668**
Filed:	**August 31, 2001**
For:	**HYBRID BALLOON EXPANDABLE/SELF-EXPANDING STENT**
Examiner:	**Jessica R. Baxter**
Group Art Unit:	**3732**

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Docket No.: S63.2-9867-US01

AMENDED APPEAL BRIEF

This is a Brief on Appeal for the above-identified application in which claims 1-4, 6-15, 30, and 33-40 were finally rejected in a Final Office Action mailed May 4, 2006. A Notice of Appeal was filed in this case on July 17, 2006. This brief is submitted in accordance with 37 C.F.R. § 41.37.

In response to the Notification of Non-Compliant Appeal Brief, Applicants have removed the status identifiers of the claims. Furthermore, with regard to the non-compliance item entitled "At least one amendment has been filed subsequent to the final rejection, and the brief does not contain a statement of the status of each such amendment", Applicants note that a Response was filed, not an Amendment. As such, Applicants believe that the statement filed in the previous brief was correct: "No amendment was filed subsequent to the final rejection of May 4, 2006." Nevertheless, Applicants have amended the brief to address the Office's concern.

The fees required under § 41.20(b)(2) and any required petition for extension of time for filing this brief therefor are dealt with in the accompanying Transmittal Letter.

(i) Real Party in Interest

The application is assigned to Boston Scientific Scimed, Inc., (former name: Scimed Life Systems, Inc.), One SciMed Place, Maple Grove, MN 55311-1566, a Minnesota

Corporation and a subsidiary of Boston Scientific Corporation, One Boston Scientific Place, Natick, Massachusetts, 01760-1537, a Delaware Corporation.

(ii) Related Appeals and Interferences

No related appeals or interferences are pending.

(iii) Status of claims

Claims 1-45 are pending. Of these, claims 5, 16-29, 31, 32, and 43 have been withdrawn. Claims 41, 42, 44, and 45 have been allowed. The claims having been rejected and which are being appealed are 1-4, 6-15, 30, and 33-40.

(iv) Status of amendments

A Response After Final was filed on June 9, 2006. The Response did not propose any amendments. The Office considered the Response but in an Advisory Action mailed June 26, 2006, stated that it did not put the application in condition for allowance.

(v) Summary of claimed subject matter

Independent claims 1, 30, and 38 pertain to a stents having frangible members. The required references to the specification and drawings are provided in brackets in the claim summaries below.

According to independent claim 1, a stent having a longitudinal axis comprising a non-woven tubular element having a plurality of openings therein is provided [p. 6, lns. 10-13; see 111 of Fig. 1]. The tubular element comprises a plurality of interconnected struts which form at least one continuous pathway which extends all the way around the longitudinal axis [p. 6, lns. 10-13; Fig. 1]. The interconnected struts have an outside surface facing outside the stent and an inner surface facing the longitudinal axis, and a side portion there between; the side portion having a thickness defined by the radial distance between the outer surface and the inner surface

[p. 10, lns. 22-25; see 121 and 123 of Fig. 9]. The stent further comprises at least one of the struts being a frangible temporary strut [p. 3, lns. 1-2]. The frangible temporary strut restrains at least two of the interconnected struts from self-expansion wherein at least a portion of the stent constructed and arranged to self-expand upon breaking of the at least one frangible temporary strut [p. 6, lns. 16-18]. The thickness of a portion of the frangible temporary strut being substantially narrower than the thickness of any other portion of the frangible temporary strut [p. 9, lns. 7-9; see 114 vs 112 of Fig. 9].

According to independent claim 30, a stent having a longitudinal axis comprising a generally non-woven tubular body having interconnected struts which form at least one continuous pathway which extends around the longitudinal axis is provided [p. 6, lns. 10-13; Fig. 1]. The interconnected struts have an outside surface facing outside the stent and an inner surface facing the longitudinal axis, and a side portion there between; the side portion having a thickness defined by the radial distance between the outer surface and the inner surface [p. 10, lns. 22-25; see 121 and 123 of Fig. 9]. The stent further comprises at least one frangible temporary strut disposed completely between at least two interconnected struts and restraining the interconnected struts from self-expansion [p. 2, lns 18-21]. At least a portion of the stent is capable of self-expanding upon breaking of the frangible temporary strut [p. 6, lns. 16-18]. The frangible temporary strut is at least partially constructed from metal [p. 8, lns. 14-17]. The thickness of a portion of the frangible temporary strut being substantially narrower than the thickness of any other portion of the frangible temporary strut [p. 9, lns. 7-9; see 114 vs 112 of Fig. 9].

According to independent claim 38, a non-woven stent formed of a plurality of interconnected struts and having a longitudinal axis is provided [p. 6, lns. 10-13]. The interconnected struts have an outside surface facing outside the stent and an inner surface facing the longitudinal axis, and a side portion there between; the side portion having a thickness defined by the radial distance between the outer surface and the inner surface [p. 10, lns. 22-25; see 121 and 123 of Fig. 9]. The interconnected struts include at least one temporary strut and permanent struts wherein the permanent struts fully defining at least one opening in the stent [p. 6, lns. 11-16; see 11 and 112 of Fig. 1]. The at least one temporary strut restrains self-expansion of at least one permanent strut about the at least one opening, and the at least one temporary strut

but not the permanent struts breaks upon the application of a predetermined outward pressure to the stent [p. 2, lns. 20-26]. The thickness of a portion of the temporary strut being substantially narrower than the thickness of any other portion of the temporary strut [p. 10, lns. 19-20; Fig. 9] At least a portion of the stent constructed and arranged to self-expand upon breaking of the at least one temporary strut [p. 2, lns. 25-26]. No portion of the temporary strut overlaps any portion of the outer surface of the permanent struts being restrained [p. 2, lns. 20-21]. The pressures selected from the group consisting of: radial pressure, axial pressure, and any combination thereof [p. 4, lns. 8-9].

(vi) Grounds of Rejection to be Reviewed on Appeal

Review on appeal is requested of the Examiner's contention that claims 1-4, 6-10, 14, 15, 30, 33, 34, and 38 are anticipated by PG-PUB 2002/0107560 to Richter.

Review on appeal is also requested of the Examiner's contention that claims 11-13, 35-37, 39, and 40 are obvious from Richter '560 in view of Lock et al. (U.S. 5,591,223).

(vii) Argument

1. The Examiner Erred in rejecting claims 1-4, 6-10, 14, 15, 30, 33, 34, and 38 are anticipated by PG-PUB 2002/0107560 to Richter.

Claims 1-4, 6-10, 14, 15, 30, 33, 34, and 38 have been rejected under 35 USC 102(e) by PG-PUB 2002/0107560 to Richter. The rejection must be reversed.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP 2131. The Examiner has not made the requisite showing.

Claims 1, 30, and 38 all require restraining self-expansion of at least a portion of the stent. In regard to this limitation the Examiner points to paragraph 0009 of Richter. However, neither this paragraph nor the remainder of the Richter application teach restraining *self-expansion* of the interconnected struts or stent.

In fact, Richter teaches detachment struts that allow the stent to detach into multiple stent segments after stent expansion (paragraph 0006 of Richter). This detachment is caused by "physiological stress" placed on the detachment struts. This physiological stress is caused by body functions of the patient (i.e. motion of the treated vessel). In addition, this breaking of the detachment struts occurs after implantation of the stent; in some instances after such a time that the segments are buried under neointima (paragraph 0008 of Richter). Thus, in the Richter reference the stent is first expanded and then the detachment struts are broken.

This is in stark contrast to independent claims 1, 30, and 38 which recite as follows:

Claim 1: "at least a portion of the stent constructed and arranged to self-expand upon breaking of the at least one frangible temporary strut";

Claim 30: "at least a portion of the stent capable of self-expanding upon breaking of the frangible temporary strut";

Claim 38: "at least a portion of the stent capable of self-expanding upon breaking of the temporary strut".

The instant claims teach self-expansion upon breaking of a strut or in some instances multiple struts. Richter fails to teach self-expansion and further fails to teach self-

expansion upon breaking a strut. Thus, Richter does not teach all the limitations of the instant claims.

For at least these reasons, reversal of the rejection under 35 USC §102(e) is respectfully requested.

2. The Examiner Erred in rejecting claims 11-13, 35-37, 39, and 40 are obvious from Richter '560 in view of Lock et al. (U.S. 5,591,223)

Claims 11-13, 35-37, 39, and 40 have been rejected under 35 USC 103 as obvious from Richter '560 in view of Lock et al. (U.S. 5,591,223).

As stated in MPEP 2143 and throughout the caselaw, "the prior art reference (or references when combined) must teach or suggest all the claim limitations."

These claims are dependent upon independent claims 1, 30, and 38. As stated above Richter does not teach the limitations of claims 1, 30, and 38. The stent of Lock is designed to allow for a second possible dilation of the stent. Pediatric patients who have had a stent implanted may need to have the stent further dilated as their lumens grow. Thus, the breakable members of Lock can be broken in order to further expand the stent. However, there is no teaching or suggestion in Lock regarding struts restraining *self-expansion* as taught in independent claims 1, 30, and 38. As stated above, Richter also fails to teach or suggest this limitation.

Therefore, even if Richter and Lock were combined in the manner proposed, the resulting hybrid would fail to teach or suggest all of the elements of the instant claims.

For at least this reason, claims 11-13, 35-37, 39, and 40 are allowable as they claim dependence upon independent claims 1, 30, and 38 which are believed to be in condition for allowance. Applicant respectfully requests that the 103(a) rejection be withdrawn.

3. Conclusion

The Examiner has failed to provide a teaching or suggestion of all the limitations of independent claims 1, 30, and 38. Thus, claims 1-4, 6-15, 30, and 33-40 are in condition for

allowance. The Board is respectfully requested to reverse the rejections with instruction to pass the application to issue.

Respectfully submitted,

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(viii) Claims Appendix

Claim 1. A stent having a longitudinal axis comprising:

a non-woven tubular element having a plurality of openings therein, the tubular element comprising a plurality of interconnected struts which form at least one continuous pathway which extends all the way around the longitudinal axis, the interconnected struts having an outside surface facing outside the stent, an inner surface facing the longitudinal axis, and a side portion there between, the side portion having a thickness defined by the radial distance between the outer surface and the inner surface; the stent further comprising at least one of the struts being a frangible temporary strut, the frangible temporary strut restraining at least two of the interconnected struts from self-expansion, at least a portion of the stent constructed and arranged to self-expand upon breaking of the at least one frangible temporary strut, the thickness of a portion of the frangible temporary strut being substantially narrower than the thickness of any other portion of the frangible temporary strut.

Claim 2. The stent of claim 1 wherein the portion of the stent which is constructed and arranged to self-expand upon breaking of the frangible temporary strut is made of a shape-memory material.

Claim 3. The stent of claim 2 wherein the shape memory material is from the group consisting of shape-memory metals and shape-memory plastics.

Claim 4. The stent of claim 1 wherein the entirety of the stent is constructed and arranged to self-expand upon breaking of the frangible temporary strut.

Claim 6. The stent of claim 1 wherein the frangible temporary strut is constructed from a different material than the interconnected struts.

Claim 7. The stent of claim 1 comprising a plurality of frangible temporary struts, each of which extends between at least two adjacent interconnected-struts.

Claim 8. The stent of claim 7 wherein the frangible temporary struts are selected from at least one member of the group consisting of: frangible welds, frangible glues, frangible solder, and any combination thereof.

Claim 9. The stent of claim 7 wherein the frangible temporary struts are distributed uniformly throughout the stent.

Claim 10. The stent of claim 7 wherein the frangible temporary struts are distributed about at least one end of the stent.

Claim 11. The stent of claim 7 wherein the stent is capable of withstanding an outward pressure of up to 2 atmospheres without breakage of the frangible temporary struts, the pressures selected from the group consisting of: radial pressure, axial pressure, and any combination thereof.

Claim 12. The stent of claim 7 wherein the stent is capable of withstanding an outward pressure of up to 5 atmospheres without breakage of the frangible temporary struts, the pressures selected from the group consisting of: radial pressure, axial pressure, and any combination thereof.

Claim 13. The stent of claim 7 wherein the stent is capable of withstanding an outward pressure of up to 12 atmospheres without breakage of the frangible temporary struts, the pressures selected from the group consisting of: radial pressure, axial pressure, and any combination thereof.

Claim 14. The stent of claim 1 wherein the frangible temporary strut includes a circumferential extending component.

Claim 15. The stent of claim 1 wherein the frangible temporary strut includes a curved portion.

Claim 30. A stent having a longitudinal axis comprising a generally non-woven tubular body having interconnected struts which form at least one continuous pathway which extends around the longitudinal axis, the interconnected struts having an outside surface facing outside the stent, an inner surface facing the longitudinal axis, and a side portion there between, the side portion having a thickness defined by the radial distance between the outer surface and the inner surface; the stent further comprising at least one frangible temporary strut disposed completely between at least two interconnected struts and restraining the interconnected struts from self-expansion, at least a portion of the stent capable of self-expanding upon breaking of the frangible temporary strut, the frangible temporary strut at least partially constructed from metal, the thickness of a portion of the frangible temporary strut being substantially narrower than the thickness of any other portion of the frangible temporary strut.

Claim 33. The stent of claim 30 comprising a plurality of frangible temporary struts.

Claim 34. The stent of claim 30 where the entirety of the stent is capable of self-expanding upon breaking of the frangible temporary strut.

Claim 35. The stent of claim 30 wherein the stent is capable of withstanding outward pressures of up to 2 atmospheres without breakage of the frangible temporary strut, the pressures selected from the group consisting of: radial pressure, axial pressure, and any combination thereof.

Claim 36. The stent of claim 30 wherein the stent is capable of withstanding outward pressures of up to 5 atmospheres without breakage of the frangible temporary strut, the pressures selected from the group consisting of: radial pressure, axial pressure, and any combination thereof.

Claim 37. The stent of claim 30 wherein the stent is capable of withstanding outward pressures of up to 12 atmospheres without breakage of the frangible temporary strut, the

pressures selected from the group consisting of: radial pressure, axial pressure, and any combination thereof.

Claim 38. A non-woven stent formed of a plurality of interconnected struts and having a longitudinal axis, the interconnected struts having an outside surface facing outside the stent, an inner surface facing the longitudinal axis, and a side portion there between, the side portion having a thickness defined by the radial distance between the outer surface and the inner surface, the interconnected struts including at least one temporary strut and permanent struts, the permanent struts fully defining at least one opening in the stent, the at least one temporary strut restraining self-expansion of at least one permanent strut about the at least one opening, the at least one temporary strut but not the permanent struts breaking upon the application of a predetermined outward pressure to the stent, the thickness of a portion of the temporary strut being substantially narrower than the thickness of any other portion of the temporary strut, at least a portion of the stent constructed and arranged to self-expand upon breaking of the at least one temporary strut, no portion of the temporary strut overlapping any portion of the outer surface of the permanent struts being restrained the pressures selected from the group consisting of: radial pressure, axial pressure, and any combination thereof.

Claim 39. The stent of claim 38 wherein the predetermined outward pressure is in excess of 2 atmospheres.

Claim 40. The stent of claim 38 wherein the predetermined outward pressure is in excess of 12 atmospheres.

(ix) Evidence appendix.

None

(x) Related proceedings appendix.

None